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Nos. 13-354 & 13-356

In the Supreme Court of the United States

KATHLEEN SEBELIUS, ET AL., *Petitioners*
v.
HOBBY LOBBY STORES, INC., ET AL., *Respondents*

CONESTOGA WOOD SPECIALTIES CORP., ET AL., *Petitioners*
v.
KATHLEEN SEBELIUS, ET AL., *Respondents*

ON WRITS OF CERTIORARI
TO THE UNITED STATES COURTS OF APPEALS
FOR THE TENTH AND THIRD CIRCUITS

BRIEF OF *AMICUS CURIAE* WOMEN SPEAK FOR THEMSELVES IN SUPPORT OF HOBBY LOBBY STORES, INC. AND CONESTOGA WOOD SPECIALTIES, ET AL.

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INTEREST OF *AMICUS CURIAE*[1]

Amicus Women Speak for Themselves is a project of the Chiaroscuro Institute and a membership organization of more than 41,000 American women who have signed an "open letter" opposing the contraception and emergency contraception mandate ("the Mandate")[2] issued by the Department of Health and Human Services ("HHS") because the Mandate threatens religious freedom and proposes a reductionist and harmful understanding of women's freedom. Members of Women Speak for Themselves bring fact-based and nonpartisan arguments about women's freedom and about religious freedom to their local communities, and to the federal government.

SUMMARY OF THE ARGUMENT

I. HHS[3] has not demonstrated a "compelling state interest" sufficient to permit the government to burden the Free Exercise rights of individuals or institutions under either the First Amendment to

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[1] No counsel for a party authored this brief in whole or in part. Printing costs for this brief were provided by the members of Women Speak for Themselves. Letters from all parties consenting to the filing of this brief have been submitted to the Clerk.

[2] 45 C.F.R. 147.130(a)(1)(iv) (2013) (HHS); 29 C.F.R. 2590.715-2713(a)(1)(iv) (2013) (Labor); 26 C.F.R. 54.9815-2713(a)(1)(iv) (2013).

[3] For simplicity, "HHS" refers to all Defendants in this action: Secretary Kathleen Sebelius, the U.S. Dept. of Health and Human Services, Secretary Hilda Solis, the U.S. Dept. of Labor, Timothy Geithner, and the U.S. Dept. of the Treasury.

the Constitution or the Religious Freedom Restoration Act,[4] by forcing them to obtain insurance coverage of contraception and emergency contraceptives ("ECs"). HHS has not demonstrated that the Mandate will improve women's health or their equal access to health services. Granting the requested exemption does not threaten the federal government's ability to uniformly administer a national program. Nonbeneficiaries of the requested exemption are not impermissibly burdened. The numerous exemptions to the Mandate indicate that HHS is not seeking to accomplish an interest it regards as of the highest order.

II. HHS argues that the Mandate primarily serves the health of children in the womb and after birth, by preventing the health damages it claims children suffer as a result of unintended or too-closely spaced pregnancies. The Affordable Care Act ("ACA"),[5] however, authorized HHS to formulate guidelines on preventive services promoting women's health. Furthermore, drugs and devices preventing children's existence or destroying children at the embryonic stage of their lives, do not promote children's health.

III. HHS cannot demonstrate that the Mandate furthers governmental interests in women's health or assuring women equal access to health services. HHS simply assumes that what contraception can do

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[4] Religious Freedom Restoration Act, Pub. L. No. 103-141, 107 Stat. 1488 (1993) (codified in scattered sections of 5 and 42 U.S.C.).

[5] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152).

on an individual scale – prevent conception or implantation of a child – it can do on a social scale; but the pertinent data indicates otherwise. The sources upon which HHS relies do not support any link in the chain of causation HHS must demonstrate. Other sources confirm this failure. To wit, HHS does not show that: the Mandate will cause an increase in the *usage* of contraceptives and ECs; that increased usage will cause lower rates of unintended pregnancy, abortion or contraindicated pregnancies; or that unintended pregnancy causes identified health problems for women. Nor does HHS demonstrate that any incidental health benefits contraception might offer outweigh acknowledged health risks some contraceptives pose to some women.

IV. HHS claims that the Mandate promotes gender equality respecting health expenses, but its sources do not show that contraceptives account for differential health costs between men and women. Furthermore, this Court should refrain from affirming HHS' argument that women's fertility and childrearing prevent their advancement and integration in American society. This argument harms the causes of women's equality and freedom.

ARGUMENT

I. HHS HAS FAILED TO DEMONSTRATE THAT THE MANDATE SERVES A "COMPELLING STATE INTEREST" ACCORDING TO THIS COURT'S DECISIONS.

The Religious Freedom Restoration Act ("RFRA") forbids the federal government from substantially burdening the exercise of religion unless the burden furthers a compelling governmental interest.[6] This requirement obtains even if the "burden results from a rule of general applicability."[7] Under the First Amendment, the state must demonstrate a compelling governmental interest in a federal or state law burdening free exercise if the law is not a "neutral law of general applicability."[8] This brief does not take up the matter of the Mandate's substantial burden on Free Exercise, nor does it address the questions of its "neutrality" or "general applicability." It rather argues that in whatever context HHS is required to demonstrate that the Mandate serves a "compelling governmental interest," HHS has failed. Neither HHS' Brief, nor the Institute of Medicine Report on which it relies so strenuously – *Clinical Preventive Services for Women: Closing the Gap* ("IOM Report")[9] – demonstrate such an interest.

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[6] 42 U.S.C. § 2000bb-1(b) (2012).

[7] 42 U.S.C. § 2000bb-1(a) (2012).

[8] *See Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 531-32 (1993).

[9] Inst. of Med., (2011) [hereinafter "IOM Report"].

HHS has the burden of "going forward with the evidence and of persuasion"[10] about the existence of a "paramount interest"[11] of the state. It has to show that this interest is satisfied by applying the challenged law to "the particular claimant whose sincere exercise of religion is being substantially burdened." [12] HHS must do more than express "broadly formulated interests."[13] If the challenged law contains exemptions for others, this is evidence that it does not "protect[] an interest 'of the highest order'... when it leaves appreciable damage to that supposedly vital interest unprohibited."[14]

Four aspects of this Court's "compelling state interest" jurisprudence indicate why the Mandate fails this test. First, HHS has allowed a dramatic number of exemptions to the Mandate. These are addressed fully in the Brief for Petitioners Conestoga Wood Specialties Corp.[15]

Second, HHS has not demonstrated that the Mandate actually forwards the government's declared interests, as required by *Brown v. Entertainment Merchants Association.* [16] HHS

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[10] *Gonzales v. O Centro Esprita Beneficente Uniao de Vegetal*, 546 U.S. 418, 428 (2006) (citation omitted).

[11] *Sherbert v. Verner*, 374 U.S. 398, 406 (1963) (quotation omitted).

[12] *Gonzales*, 546 U.S. at 430-31.

[13] *Id.* at 431.

[14] *Church of Lukumi Babalu Aye, Inc. v. Hialeah*, *supra*, at 547 (quoting *Florida Star v. B. J. F.*, 491 U.S. 524, 541-42 (1989) (Scalia, J., concurring in part and concurring in judgment)).

[15] *See* Brief for Petitioner at 44-45, *Conestoga Wood Specialties Corp. v. Kathleen Sebelius*, No. 13-354 (U.S. Sup. Ct., Jan. 10, 2014).

[16] *Brown v. Entm't Merchs. Ass'n*, 131 S. Ct. 2729 (2011).

cannot demonstrate a causal connection between the Mandate and its claimed health outcomes. (See Sections II. and III.) *Brown* requires that the state "specifically identify an 'actual problem' in need of solving," and show that the burden on the constitutional right is "actually necessary" to the solution.[17] It may not make a merely "predictive judgment" about a causal link based upon competing studies.[18] It may not rely upon "ambiguous proof,"[19] but must "prove" that the matter it regulates is the "cause" of the harm it seeks to prevent. Evidence of mere "correlation" is insufficient, as are studies with "significant, admitted flaws in methodology."[20] Even if the state proves causation, evidence that the claimed effects are "small" and "indistinguishable" from effects produced by things *not* regulated, renders the legislation "underinclusive."[21] The state must show more than a "modest gap" (20% in *Brown*) between the government's goal and the current situation; "the government does not have a compelling interest in each marginal percentage point by which its goals are advanced."[22]

Under *Brown*, HHS has failed to demonstrate a compelling state interest in applying the Mandate to the religiously objecting parties. HHS uses an uncertain measure of "unintended pregnancy," and offers a merely "predictive judgment" of a causal link between free contraception and improved health for women. (See Section III.) Additionally, HHS

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[17] *Id.* at 2738.
[18] *Id.*
[19] *Id.* at 2739.
[20] *Id.*
[21] *Id.* at 2740.
[22] *Id.* at 2741, n.9.

proposes that the law predominantly assists children's health, though women's health is the Mandate's ACA-authorized goal. (See Section II.) HHS also rests its findings about women's health on a few studies which do not support its causal claims, and ignores competing studies. HHS proposes to close a relatively small (11%) gap in contraceptive usage with extensive regulations which would not likely succeed in assisting at least the following groups of women: those for whom contraceptives are medically contraindicated; those who object on religious or moral grounds; those who fear certain health risks or side effects; and those who eschew contraceptives, not because of cost, but because of the many other reasons women usually cite. In sum, contraception is virtually ubiquitous. The Mandate is directed to women already using contraception at high rates, and does not address the many reasons other than cost why a small group of women choose not to use contraception. HHS has demonstrated nothing more than the theoretical possibility that the Mandate might increase contraceptive usage. This is legally insufficient. (See Section III. A.)

Even if the Mandate could increase usage among any group of women, it is not clear that this would achieve lower rates of unintended pregnancy or abortion. Contraceptive failure rates are significant. Rates of unintended pregnancy and abortion have fluctuated over the past decades in response to many different variables. Credible analyses show that "risk compensation" effects, among other reasons, have and may continue to produce higher, not lower rates of unintended pregnancy and abortions in response to changes in contraceptives' availability. (See Section III.B.)

Finally, even if HHS could show that the Mandate could increase contraceptive usage *and* reduce rates of unintended pregnancies, HHS does not demonstrate a causal relationship between unintended pregnancies and women's health. Its cited sources and others suggest mere correlation, or reverse causation, or the presence of a third factor driving both unintended pregnancies and particular health outcomes. (See Section III.C.)

In sum, HHS' argument is exactly the kind of "ambiguous proof" the *Brown* Court rejected. HHS also fails the *Brown* test of "underinclusivity" as laws addressing matters HHS leaves *unregulated* might better ameliorate women's health and health care costs. HHS could devote more resources, for example, to maternity costs – the leading driver of differential health costs between males and female of childbearing ages[23] – or children's health care costs, given women's higher rates of single parenting.[24]

To the extent that HHS intends the Mandate to further a governmental interest in reducing unintended pregnancy by moving more women to more expensive and effective long-acting reversible

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[23] Ctrs. for Medicare & Medicaid Servs., *National Health Care Spending by Gender and Age, 2004 Highlights* (2004), http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/2004GenderandAgeHighlights.pdf.

[24] Jonathan Vespa et al., (U.S. Census Bureau), *America's Families and Living Arrangements: 2012*, 12, Table 4 (2013).

contraceptives ("LARCs"),[25] this plan is uncertain. The conditions under which this plan would succeed among women touched by the Mandate are unknown; it also raises moral hazards involving the government's treatment of vulnerable women. (See Section III.A.)

Third, HHS cannot claim a compelling governmental interest of the kind at issue in *United States v. Lee.*[26] Though the Internal Revenue Service ("IRS") will administer penalties for noncompliance with the Mandate, the social security and national taxation systems at issue in *Lee* are not at all analogous to the business-to-business insurance transaction the Mandate compels. HHS' granting an exemption from the Mandate is nothing like Congress or the IRS compromising the "fiscal vitality" of the "largest domestic governmental program,"– a program determined by a "complex of actuarial factors" – by allowing nonpayment.[27] Furthermore, unlike the taxation systems at issue in *Lee*, the Mandate was not legislated by Congress; it is a discretionary initiative by HHS (which relied upon the recommendations of a conspicuously ideological IOM committee[28]). There is also no likelihood of a "slippery slope," as in *Lee.* An

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[25] Defendant's Memorandum at 7, ECF 41, *Hobby Lobby Stores, Inc. v. Sebelius*, 870 F. Supp.2d 1278 (W.D. Okla. 2012) [hereinafter "Def. Mem."].

[26] *United States v. Lee*, 455 U.S. 252 (1982).

[27] 455 U.S. at 258-59.

[28] Letter from Anna Franzonello, Ams. United for Life, to Ctrs. for Medicare and Medicaid Servs. (Sept. 29, 2011), http://www.freedom2care.org/docLib/20110929_AmericansUnitedforLifepreventiveservicescomment.pdf.

exemption from insuring contraception is not at all analogous to absolving beneficiaries from tax liability: HHS acknowledges the near universality of contraception coverage already,[29] and claims that such coverage is cheaper for businesses and insurers than caring for born children.[30]

Fourth, the requested accommodation does not override nonbeneficiaries' significant interests.[31] Employees working for religious employers are more likely to share such religious commitments. Contraception is ubiquitous and relatively inexpensive.[32] Efforts to insist upon its even greater availability or lower cost are spearheaded by interest groups like Planned Parenthood, not grassroots groups of female employees. Finally, HHS has already communicated that an exemption does not significantly burden nonbeneficiaries by means of the volume of exemptions it already allows.

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[29] Press Release, Dep't of Health & Human Servs., *A Statement by U.S. Dept. of Health and Human Services Kathleen Sebelius* (Jan. 20, 2012), http://www.hhs.gov/news/press/2012pres/01/20120120a.html.

[30] Brief of Respondent at 7, *Conestoga Wood Specialties Corp. v. Sebelius*, No. 13-354 (U.S. Sup. Ct., Jan. 10, 2014).

[31] *Cutter v. Wilkinson*, 544 U.S. 709, 722 (2005).

[32] *See generally* Kimberly Palmer, *The Real Cost of Birth Control*, U.S. News & World Rep. (Mar. 5, 2012), http://money.usnews.com/money/blogs/alpha-consumer/2012/03/05/the-real-cost-of-birth-control.

II. HHS' CLAIMS THAT FREE CONTRACEPTIVES AND EMERGENCY CONTRACEPTIVES WILL IMPROVE CHILDREN'S HEALTH ARE INAPPOSITE OR NONSENSICAL.

Although HHS regularly claims that *women's* health is the primary interest underlying the Mandate, nearly every specific interest HHS relies upon involves *children's* health. To wit, HHS claims that free contraception and ECs, by reducing the number of unintended and too-closely spaced pregnancies, can prevent children's premature birth, low birth weight, and the effects upon children of mothers' delayed entry into prenatal care, and smoking and consuming alcohol during pregnancy.[33] The section of the ACA authorizing the Mandate, however, empowered HHS to delineate preventive health services for *women,* not children. Furthermore, is it nonsensical for HHS to claim that contraceptives and ECs – which prevent children's existence, or destroy their lives at the embryonic stage – constitute preventive services *for* children.

The ACA required certain health plans and health insurance issuers to cover certain preventive services for women, without a co-pay. These were to include "preventive care and screenings ... as provided for in comprehensive guidelines supported by the Health Resources Services Administration" (an HHS agency).[34] HHS thereafter commissioned

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[33] Brief for Petitioner at 47, *Sebelius v. Hobby Lobby Stores, Inc.*, No. 13-356 (U.S. Sup. Ct., Jan. 10, 2014) (citing IOM Report at 103) [hereinafter "Brief for Pet."].

[34] 42 U.S.C. § 300gg-13(a)(4) (2006).

the Institute of Medicine ("IOM") to "convene an expert committee for the "development of comprehensive *guidelines for preventive services for women.*" [35] That committee recommended the provision, without cost-sharing, of "the full range of Food and Drug Administration-approved ["FDA"] contraceptive methods," including drugs taken after intercourse, "ECs."[36]

As detailed above, despite Congress' charge to HHS to develop guidelines "for women," HHS asserts that its main interests underlying the Mandate concern the health of children, both in the womb and after birth. Even were children's health within the ambit of HHS' authority, however, it is nonsensical for HHS to suggest that contraception and ECs improve children's health; they act rather to prevent children's conception or their implantation into their mother's womb at their embryonic stage. HHS freely admits these drug actions. Secretary Sebelius stated regarding ECs: "These covered prescription drugs are specifically those that are designed *to prevent implantation.*" [37] The Food and Drug Administration (FDA), [38] EC manufacturers, and

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[35] IOM Report, *supra*, at 2 (emphasis added).

[36] *Id.* at 109-110.

[37] Kelly Wallace, *Health and Human Services Secretary Kathleen Sebelius Tells iVillage "Historic" New Guidelines Cover Contraception, Not Abortion*, IVILLAGE (Aug. 2, 2011), http://www.ivillage.com/kathleen-sebelius-guidelines-cover-contraception- not-abortion/4-a-369771 (alteration in original) (emphasis added).

[38] *See* How Does Plan B One-Step Work?, http://www.planbonestep.com/faqs.aspx; Food & Drug Admin., Plan B Approved Labeling (2006), http://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021045s011_; Plan_B_Prntlbl.Pdf; Watson Pharm., Inc., Ella Labeling

extant scientific literature confirm this.[39] Of course when an embryo cannot implant in the mother's womb, it perishes.

Furthermore, even if HHS could argue that a mandate directed to children's health was authorized by the ACA, and even if this Court accepted that preventing children's existence or development promotes their health, the sources HHS cites for the claimed nexus between unintended pregnancy and adverse outcomes for children do not support its claim. They are either unrelated to children's health,[40] or claim only to prove "association" not causation.[41] The earlier IOM report HHS cites concerning women's smoking and drinking during unintended pregnancy also does not assert causation, and notes that even figures "associating" unintended pregnancy with mothers' smoking and

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Information (2010), http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf.

[39] Susan Wills, *New Studies Show All Emergency Contraceptives Can Cause Early Abortion*, Charlotte Lozier Inst. (Jan. 2014), http://www.lozierinstitute.org/wp-content/uploads/2014/01/On-Point-Wills-Emergency-Contraception-Jan-2014-.pdf.

[40] Baiju R. Shah, et al., *Increased Risk of Cardiovascular Disease in Young Women Following Gestational Diabetes Mellitus*, 31 Diabetes Care 1668 (2008) (cited by IOM Report at 103).

[41] Agustin Conde-Agudelo et al., *Birth Spacing and Risk of Adverse Perinatal Outcomes: A Meta-Analysis*, 295 J. Am. Med. Ass'n 1809 (2006); Elena Fuentes-Afflick & N. A. Hessol, *Interpregnancy Interval and the Risk of Premature Infants*, 95 Obstetrics & Gynecology 383 (2000); Bao Ping Zhu, et al., *Effect of Interpregnancy Interval on Birth Outcomes: Findings from Three Recent U.S. Studies*, 89 Int'l J. Gynecology & Obstetrics S25, S25–S33 (2005).

drinking "drop significantly where studies control for other causes." [42] Other studies indicate possible reverse causation or a third factor – women's risk-taking preferences – accounting both for unintended pregnancy and smoking and drinking during pregnancy.[43] Finally, almost all mothers who smoke during pregnancy smoked before pregnancy.[44]

III. HHS HAS FAILED TO DEMONSTRATE A CAUSAL RELATIONSHIP BETWEEN THE MANDATE AND IMPROVED HEALTH FOR WOMEN.

HHS' Brief contends that the Mandate furthers the state's interest in promoting women's health by helping avert pregnancy among women with particular conditions contraindicating pregnancy – pulmonary hypertension, cyanotic heart disease, and Marfan Syndrome.[45] HHS also claims that some contraceptives can prevent health problems like cancers, menstrual disorders and pelvic pain, [46] as well as lower abortion rates. [47] Finally, HHS asserts that contraceptives' ability to

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[42] Inst. of Med., *The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families* (1995), 68-69, 75 [hereinafter "IOM 1995 Report"].

[43] Timothy S. Naimi et al., *Binge Drinking in the Preconception Period and the Risk of Unintended Pregnancy: Implications for Women and Their Children*, 111 Pediatrics 1136 (2003); Carolyn Westhoff et al., *Smoking and Oral Contraceptive Continuation*, 79 Contraception 375 (2009); Gregory J. Colman & Ted Joyce, *Trends in Smoking Before, During, and After Pregnancy in Ten States*, 24 Am. J. Preventive Med. 29 (2003).

[44] Colman & Joyce, *supra*, at 29-35.

[45] Brief for Pet. at 47 (citing IOM Report at 103-04).

[46] *Id.* (citing IOM Report at 107).

[47] Brief for Pet. at 47.

"reduc[e] the incidence of unintended pregnancies" on a national scale will benefit women. HHS' Brief, however, cites *no* related health benefits for women, flowing from the hoped-for reduction in unintended pregnancy;[48] the interest it states there in helping women avoid smoking and alcohol during pregnancy, is linked with avoiding harm to unborn children.[49] At the start of this litigation, HHS did claim that unintended pregnancies lead to the following negative health outcomes for women: depression, domestic violence, and consuming cigarettes and alcohol.[50] In the event this Court considers these now-missing claims, Section III.C. treats them, *infra*.

HHS relies nearly exclusively upon the IOM Report to support its claims, but this report offers remarkably few relevant sources for HHS' sweeping claims about linkages between: cost and increased usage of contraception; and increased usage and reducing unintended pregnancies and abortions. Instead, HHS is relying upon an assumption that widespread free contraception and ECs must accomplish on a national level what they are designed to do on an individual level. The subsections below will demonstrate, however, that each link in this causal chain is unsupported or contradicted by the evidence.

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[48] Brief for Pet. at 46, 48.

[49] *Id.* at 47 (citing IOM Report at 103).

[50] Def. Mem. at 8.

A. HHS does not show that the Mandate will cause increased usage of contraceptives or ECs, especially among women at risk for unintended pregnancy and abortion.

HHS claims that cost prevents many women from using contraceptives and ECs [51] and that insurance coverage without cost-sharing, is *"necessary to increase the use of these services."* [52] There are myriad problems with this contention. First, the IOM Report and its sources acknowledge that contraceptive usage is already extremely high, having been used by 99% of women who have "ever" had sex, and 89% of currently sexually-active women.[53]

Second, because the Mandate is directed to employed women and daughters of the employed, it will largely affect women who already have relatively easy access to contraception and use it. Women above 150% of the poverty line and more-educated women are more likely to use contraception than less-advantaged women.[54] Also, the IOM Report acknowledges that contraceptive coverage is already "standard practice for most private insurance," [55] with nine of ten employer-based insurance plans including coverage. [56] Guttmacher Institute

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[51] Pet. for Cert. at 8. (citing IOM Report at 19 and 109).

[52] *Id.* at 7-8 (citing IOM Report at 102-03) (emphasis added).

[53] IOM Report at103; and William D. Mosher & Jo Jones, U.S. Dep't of Health and Human Servs., *Use of Contraception in the U.S.: 1982-2008*, 5, 9 (2010).

[54] Mosher & Jones, *supra*, at 25.

[55] IOM Report at 108.

[56] *Id.*

testimony before the IOM committee claimed further that "almost every reversible and permanent contraceptive method available" is covered by 90% of plans.[57] On these facts, it is difficult to imagine how the Mandate could increase the usage rates of its target audience much if at all.

The Mandate is not directed to increasing usage among the unemployed, who are disproportionately poor, young, and minority women.[58] But these groups are already amply provided free contraception through government programs. Since 1970, they have been served by the National Family Planning Program ("Title X").[59] In 2010, Title X-funded sites served more than 5 million patients – 69% at or below the poverty level and 31% above – at 4,389 service sites in all 50 states and the District of Columbia.[60] Likewise, both Title XIX of the Social Security Act (Medicaid) and Title XX of the Social Security Act[61] provide federal funds to states for pregnancy prevention services among both adolescents and adults.[62] The federal Maternal and

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[57] Testimony of Guttmacher Inst., Comm. on Preventive Servs. for Women (Jan. 12, 2011), http://www.guttmacher.org/pubs/CPSW-testimony.pdf (citing Gary Claxton, et al., *Employer Health Benefits: 2010 Annual Survey*, Kaiser Family Found. (2012), http://ehbs.kff.org/pdf/2010/8085.pdf.).

[58] IOM Report at 102.

[59] 42 U.S.C. § 300 (2006).

[60] Christina Fowler et al., *RTI Int'l, Family Planning Annual Report: 2010 National Summary*, 1, 7-8, 21 (2011), http://www.hhs.gov/opa/ pdfs/fpar-2010-national-summary.pdf.

[61] 42 U.S.C. § 1396r-1c *et seq.* (2010).

[62] *See also* Guttmacher Inst. & Kaiser Family Found., *Medicaid: A Critical Source Of Support For Family Planning In The United States* (2005),

Child Health Block Grant funds 610 school-based or school-linked health clinics.[63] In 2012, Planned Parenthood Federation of America alone received 540 million dollars of government grants and reimbursements directed largely to providing lower-cost contraception.[64]

Consequently, in order to demonstrate that the Mandate would boost usage of contraceptives and ECs, and eventually lower unintended pregnancy rates, HHS would have to demonstrate that the Mandate could affect the contraception usage of some group of women *other* than those described above – i.e. portions of the target audience who are not already using contraception at high rates, not eligible for extant government programs, not opposed to contraception due to its health risks and side effects, price-sensitive, and thus susceptible to offers of free contraceptives. But the Mandate on its face is not crafted to reach such a group.

Furthermore, evidence indicates that "cost" plays a small role in women's decisions about contraception. In Centers for Disease Control ("CDC") data cited in the IOM Report, cost does not even make the list of "frequently cited reasons for nonuse" among the 11% of sexually-active women

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http://www.kff.org/womenshealth/upload/Medicaid-A-Critical-Source-of-Support-for-Family-Planning-in-the-United-States-Issue-Brief-UPDATE. pdf.

[63] 42 U.S.C. §§ 701–710 (2010), *amended by* Pub. L. No. 112-240, 126 Stat. 2313 (2012).

[64] Planned Parenthood Fed'n of Am., *Annual Report: 2012-2013*, 8 (2013), http://www.plannedparenthood.org/files/AR-FY13_111213_vF_rev3_ISSUU.pdf.

not using contraception.[65] Leading reasons rather include everything from "didn't think she could get pregnant" (44%), to "worried about the side effects" (16%). Cost also did not figure into adolescents' "most frequently cited reasons for not using contraceptives" in another study.[66] In a Guttmacher source the IOM Report overlooked,[67] only 3.7% of the total sample of women seeking abortions listed cost as a barrier to contraceptive usage. The study's authors did not investigate if some of these women were eligible for state contraception programs.

In support of its claim about the nexus between free contraception and increased usage, HHS constantly cites[68] page 19 of the IOM Report. The sources cited there, however, consider cost as a factor affecting *both* men and women,[69] or preventive health care *generally*, not contraception or ECs.[70]

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[65] Mosher & Jones, *supra*, at 6, 14 (cited by IOM at 103).

[66] Catherine Stevens-Simon et al., *Why Pregnant Adolescents Say They Did Not Use Contraceptives Prior to Conception*, 19 J. Adolescent Health 48 (1996).

[67] Rachel K. Jones et al., *Contraceptive Use Among U.S. Women Having Abortions in 2000-2001*, 34 Persp. on Sexual & Reprod. Health 294, 297-98 (2002).

[68] Def. Mem. at 7; Brief for Pet. at 50; Pet. for Cert. at 5, 6.

[69] Henry J. Kaiser Family Found., *Impact Of Health Reform On Women's Access To Coverage And Care* 3 (2010), http://www.kff.org/women- shealth/upload/7987.pdf.

[70] *See* IOM Report at 19 (citing Sheila D. Rustgi et al., *Women at risk: Why many women are forgoing needed health care* (The Commonwealth Fund (2009)); Geetesh Solanki et al., *The direct and indirect effects of cost sharing on the use of preventive services*, 34 Health Services Research 1331 (2000); Amal N. Trivedi et al., *Effect of cost sharing on screening mammography in Medicare health plans*, 358 New Eng. J. of Med. 375 (2008) (considering, collectively, cancer screenings, dental exams, mammograms, and Pap smears).

The other sources cited in the IOM Report [71] regarding the nexus between cost and usage are also unavailing. The cited Hudman and O'Malley article[72] does not address contraception, and acknowledges that studies do not consistently find any link between cost-sharing and usage.

Both HHS' earlier submissions in this litigation,[73] and the IOM Report,[74] suggest that one of the Mandate's goals might be to increase usage of LARCs "especially among poor and low-income women most at risk for unintended pregnancy."[75] The Mandate is not, however, directed to these groups of women; and the economically more privileged women to whom it is targeted already use LARCs more.[76] If the HHS does intend the Mandate to incentivize LARCs among some group of lesser-income women and girls, however, two things should be noted. First, while LARCs may have a higher initial cost, over time they can be cheaper than initially-cheaper barrier methods.[77]

Second, there are moral and health hazards associated with such a scheme. These were

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[71] IOM Report at 109.

[72] IOM Report at 109 (citing Julie Hudman & Molly O'Malley, Henry J. Kaiser Family Found., *Health Insurance Premiums and Cost-Sharing: Findings From the Research On Low-Income Populations*, 1 (2003), http://www.kff.org/medicaid/upload/Health-Insurance-Premiums-and-Cost-Sharing-Findings-from-the-Research-on-Low-Income-Populations- Policy-Brief.pdf.

[73] Def. Mem. at 7.

[74] IOM Report at 109.

[75] IOM Report at 109.

[76] Mosher & Jones, *supra*, at 35.

[77] *See The Real Costs of Birth Control*, *supra*.

highlighted in a study offering free LARCs to mostly poor, minority, post-abortive and less-educated women in St. Louis,[78] which study was hailed widely as evidence of the logic of the Mandate.[79] There, researchers persuaded a large number of women to adopt LARCs (moving adoption of LARCs from 5% to 75%), and contacted each woman 7 times to monitor continued usage. While the study's empirical methods have been doubted,[80] it did appear to show that persuading women at risk of unintended pregnancy to become virtually sterilized for three to ten years, reduces pregnancy and abortion rates.

But the study demonstrated the health risks and moral hazards of such a strategy too. First, LARCs are associated with various adverse health outcomes, especially IUDs,[81] and Depo-Provera: the latter is linked with doubling HIV transmission rates.[82] Second, LARCs do not protect against

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[78] Jeffrey F. Peipert et al., *Preventing unintended pregnancies by providing no-cost contraception*, 120 J. Obstet. Gyn. 1291 (2012), www.ncbi.nlm.nih.gov/pubmed/23168752.

[79] *See, e.g.*, Tara Culp-Ressler, *New Study Confirms Obamacare's Birth Control Mandate will Reduce Abortion Rate*, ThinkProgress (Oct. 5, 2012), http://thinkprogress.org/health/2012/10/05/966121/obamacare-birth-control-abortion/.

[80] Michael J. New, *New Study Exaggerates Benefits of No-Cost Contraception,* Nat'l Rev. Online (Oct. 10, 2012), www.nationalreview.com/corner/329898/ new-study-exaggerates-benefits-no-cost-contraception-michael-j-new.

[81] Tessa Madden, *Risk of Bacterial Vaginosis in Users of the Intrauterine Device: A Longitudinal Study*, 39 Sex. Trans. Diseases 217 (2012).

[82] Renee Heffron et al., *Use of Hormonal Contraceptives and risk of HIV-1 Transmission: A Prospective Cohort Study*, 12 Lancet Infec. Dis. 19 (2012).

sexually transmitted infections ("STIs").[83] In St. Louis, STIs spiked noticeably during the study.[84] Third, women using LARCs may be more likely to believe that all relevant consequences of sex – emotional, psychological, and physical – are being managed, when they are not. These can have long-run negative impacts upon the health of girls and women.

B. Even if the Mandate could increase usage of contraceptives and ECs, HHS does not demonstrate that this will lead to lower rates of unintended pregnancy and abortion.

HHS asserts that "free" contraception and ECs will lead to lower rates of unintended pregnancies and abortions,[85] but offers no reliable evidence for this claim. First, the difficulty of measuring "unintended pregnancies," is well known,[86] as conceded by the 1995 IOM Report.[87] "Unintended" can mean unwanted or mistimed. Interpretation and memory can change over time. Partners can disagree. The one and only study relied upon by the IOM Report and HHS to claim a current

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[83] Planned Parenthood, *Should you Choose Long-acting Reversible Contraception?* (2014), https://www.plannedparenthood.org/ppmh/long-acting-reversible-contraception-right-you-41717.htm.

[84] Ctrs. for Disease Control, Div. of STD Prevention, *Sexually Transmitted Disease Surveillance 2010,* 93-95, 113, 119-20, 127, 129 (2011), http://www.cdc/gov/std/stats10/surv2010.pdf. [hereinafter "CDC STDs 2010"].

[85] Brief for Pet. at 47.

[86] Jessica D. Gipson, et al., *The effects of unintended pregnancy on infant, child, and parental health: a review of the literature,* 39 Studies in Family Planning 18 (2008).

[87] IOM Report 1995, *supra*, at 21-25.

49% unintended pregnancy rate[88] suffers such flaws. Its conclusion is the product of numerous questionable assumptions. To reach the sum total of "unintended pregnancies," the authors added together "unwanted" and "mistimed" pregnancies, to pregnancies toward which the woman was "indifferent." To this figure they added their own abortion estimate.

Second, the materials HHS relies upon to make this causal claim, as well as pertinent materials HHS ignores, show rising rates of unintended pregnancies and abortions over some periods of time during which contraceptive usage was rising. This is not only due to contraceptive and EC failure rates, and the wide variety of factors affecting pregnancy and abortion rates, but possibly also because of the phenomenon of risk compensation.

Concerning contraceptive failure, the CDC estimates that 12.4% of all women using contraception will become pregnant each year.[89] Thus, even if the Mandate could boost contraceptive usage, contraceptive failure will constrain reductions in pregnancy.

Also, about half of all unintended pregnancies occur among women who *are* using contraception[90];

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[88] Lawrence B. Finer & Stanley K. Henshaw, *Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001*, 38 Persp. on Sexual Reprod. Health 90 (2006).

[89] Mosher & Jones, *supra*, at 4.

[90] Guttmacher Inst., *Facts on Unintended Pregnancy in the United States*, 4 (2012), www.guttmacher.org/pubs/FB-Unintended-Pregnancy-US.html.

they result from method failure, or incorrect use. This dramatically limits the potential for increased usage to reduce unintended pregnancies. This potential is further limited given that unintended pregnancies are highly concentrated among women the Mandate will *not* affect: the poor. Guttmacher reports that they have six times the rate of unintended pregnancy of women at 200% or more of the poverty line.[91] The latter are the women most likely affected by the Mandate.

Fourth and finally, a significant body of literature suggests that rendering contraception and ECs more accessible can drive rates of unintended pregnancy and abortion up, not down, due to "risk compensation" effects whereby individuals who believe they are insured against risk, engage in more, not less, risky behavior. One widely cited study suggests that this helps explain how access to contraception decreases teen pregnancy in the short run, but increases it in the long run.[92] Programs promoting ECs (covered by the Mandate) to teens are disturbingly and regularly associated with increases in teen pregnancy and abortion rates.[93] In a meta-

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[91] Guttmacher Institute, *Unintended Pregnancy in the United States* (Dec. 2013), http://www.guttmacher.org/pubs/FB-Unintended-Pregnancy-US.html.

[92] Peter Arcidiacono et al., *Habit Persistence And Teen Sex: Could Increased Access To Contraception Have Unintended Consequences For Teen Pregnancies?* (2005), http://public.econ.duke.edu/~psarcidi/addic ted13.pdf.

[93] Jose Luis Duenas et al., *Trends in the Use of Contraceptive Methods and Voluntary Interruption of Pregnancy in the Spanish Population during 1997-2007*, 83 Contraception 82 (2011) (over ten years in Spain, a 63% increase in contraceptive use was accompanied by a 108% increase in abortion rate); *see*

analysis of 23 studies, Princeton's Dr. Trussel (upon whom the IOM relies[94]) concluded that "*no* study has shown that increased access to [Plan B, an EC] reduces unintended pregnancy or abortion rates on a population level."[95] A study cited by the IOM Report concludes similarly.[96] Furthermore, it has been recently disclosed that well-known forms of ECs are less effective for women whose weight approximates the "average" American woman,[97] and "completely ineffective" for women weighing 11 pounds more than this.

Regarding adults, a growing body of scholarship[98] indicates that the persistence or worsening of high rates of unintended pregnancy, abortion, STIs, and nonmarital births are the "logical" results of the new marketplace for sex and marriage made possible by increasingly available contraception and legal abortion. In perhaps the

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also David Paton, *The Economics of Family Planning and Underage Conceptions,* 21 J. Health Econ. 207 (2002).

[94] IOM Report at 108.

[95] Elizabeth G. Raymond, et al., *Population Effect of Increased Access to Emergency Contraceptive Pills: A Systematic Review,* 109 Obstetrics & Gynecology 181 (2007) (emphasis added).

[96] IOM Report at 108 (citing Debbie Postlethwaite, et al., *A comparison of contraceptive procurement pre-and post-benefit change,* 76 Contraception 360, 363 (2007)).

[97] Molly Redden, *New Warning: Morning-After Pill Doesn't Work for Women Over 176 Pounds,* Mother Jones (Nov. 25, 2013), http://www.motherjones.com/environment/2013/11/plan-b-morning-after-pill-weight-limit-pounds.

[98] John Richens et al., *Condoms and Seat Belts: the Parallels and the Lessons,* 355 The Lancet 400 (2000); Michael M. Cassell et al., *Risk compensation: the Achilles' heel of innovations in HIV prevention?,* 332 Brit. Med. J. 605 (2006), www.bmj.com/cgi/pdf_extract/332/7541/605?ct.; Timothy Reichert, *Bitter Pill,* 203 First Things 25 (2010).

most well-known paper on this subject, *An Analysis of Out-of-Wedlock Childbearing in the United States,*[99] author Janet Yellen and other economists describe women's immiseration via increased participation in nonmarital sexual relations without any expectation of marriage, as a result of the "technology shock" constituted by the increased availability of both contraception and abortion, which increase expectations that sex must constitute a part of a nonmarital romantic relationship. HHS never considers this literature.

In fact, HHS cites *no* sources in its Brief for the claim that greater usage of contraception will reduce unintended pregnancies nationally; it simply assumes this causation. In the IOM Report upon which HHS usually relies, however, two studies are cited:[100] one by Santelli and Melnikas[101] and the other by Guttmacher.[102] Neither considers the entire U.S. population for all the years in which access to contraception has expanded, but only portions of the population over selected periods of time.[103] Neither claims to demonstrate a causal link between contraceptive usage and lowered rates of unintended pregnancy. Santelli and Melnikas claim only an

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[99] George A. Akerlof, Janet L. Yellen & Michael L. Katz, *An Analysis of Out-of-Wedlock Childbearing in the United States,* 111 Q.J. Econ. 277 (1996).

[100] IOM Report at 105.

[101] John S. Santelli & Andrea J. Melnikas, *Teen Fertility in Transition: Recent and Historic Trends in the United States,* 31 Ann. Rev. Pub. Health 371 (2010).

[102] Heather D. Boonstra et al. (Guttmacher Inst.), *Abortion In Women's Lives* (2006), http://www.guttmacher.org/pubs/2006/05/04/AiWL. pdf.

[103] Santelli & Melnikas (teens from 1990s to early 2000s); Guttmacher (unmarried women, 1982 - 2002).

"association," not causation, [104] and concede that they "do *not attempt to resolve this debate" about the "causes and consequences of teen pregnancy."*[105] They also acknowledge the phenomenon of risk compensation, [106] and the many factors that may influence teen pregnancy rates. [107] They estimate that abstinence, not contraception, contributed to at least 50% of the reported decline in teen pregnancy rates. [108] (Other scholars believe the figure is higher.[109])

The cited Guttmacher study also does not show that increased contraception usage helped reduce rates of unintended pregnancy. It states rather that "the decline in unintended pregnancy in the U.S. seems to have stalled," even with "nearly universal" use of contraceptives. [110] Two other Guttmacher studies show unintended pregnancy rates rising from 44.7% in 1994[111] to 51% by 2001, and remaining flat or edging higher through 2006,[112]

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[104] *Id.*

[105] Santelli & Melnikas, *supra*, at 373, 377–78 (emphasis added).

[106] *Id.* at 375.

[107] *Id.* at 377-79 (mentioning the economy, population composition, family dynamics, social mores, the HIV/AIDS pandemic, and the media).

[108] *Id.* at 376.

[109] Joanna K. Mohn, Lynne R. Tingle & Reginald Finger, *An Analysis of the Causes of the Decline in Non-Marital Birth and Pregnancy Rates for Teens from 1991 to 1995,* 3 Adolesc. & Fam. Health 39 (2003) (67% attributed to abstinence and reduced sexual activity).

[110] Boonstra, *supra*, at 32.

[111] Stanley K. Henshaw, *Unintended Pregnancy in the United States,* 30 Fam. Plan. Persp. 24 (1998).

[112] Lawrence B. Finer & Stanley K. Henshaw, *Disparities in Rates of Unintended Pregnancy in the United States, 1994 and*

during the period when women's contraceptives usage *increased* from 80% to 86%.[113] A Guttmacher journal also reports that during the period from the 1970s to today — a period during which Guttmacher and the CDC agree that the percentage of women who had "ever used" contraception rose from about 90% to 99% — unintended pregnancy rates nationally rose from 35.4% to 49%.[114]

A CDC report tracking contraception usage from 1982 to 2008 concluded that "[c]hanges in contraceptive method choice and use have not decreased the *overall* proportion of pregnancies that are unintended between 1995 and 2008."[115] Another Guttmacher report on unintended pregnancy between 2001 and 2006, reached the same conclusion,[116] despite CDC data showing that more women in the years between 2002 and 2008 were accessing "more effective" methods of contraception.[117]

2001, 38 Persp. on Sexual Reprod. Health 90 (2006); Mosher & Jones, *supra*, at 376-77.

[113] IOM Report at 105 (citing Boonstra et al., *supra*, at 18).

[114] Christopher Tietze, *Unintended Pregnancies in the United States, 1970-1972,* 11 Fam. Plan. Persp. 186, 186 n.* (1979) ("A recent report estimates that in 1972, 35.4% percent of all U.S. pregnancies were 'unwanted' or 'wanted later,' thus providing, from an independent source, an estimate very close to the one used here.").

[115] Jo Jones, William Mosher & Kimberly Daniels, *Current Contraceptive Use in the United States, 2006-2010, and Changes in Patterns of Use Since 1995,* Nat'l Health Stat. Rep., 1, 11 (Oct. 2012), http://www.cdc.gov/nchs/data/nhsr/nhsr060.pdf.

[116] Lawrence B. Finer & Mia R. Zolna, *Unintended Pregnancy in the United States: Incidence and Disparities: 2006,* 84 Contraception 478 (2011).

[117] Mosher & Jones, *supra*, at 5.

It should also be remembered that the rise in unintended pregnancy rates from 44.7% to 51% between 1994 and 2001 — before they settled at about 49% from 2001 to 2006 — occurred during a time period when twenty-eight states passed contraceptive insurance mandates [118] for private insurance coverage.[119] There are also a wide range of influences upon rates of unintended pregnancy (e.g. poverty, cohabitation, later marriage, and the destigmatizing of nonmarital sex and parenting[120]). HHS never mentions these or asks whether the studies cited by the IOM Report controlled for them.

Other studies HHS overlooks question or contradict its claims about the national effects of increased contraception usage. IOM's 1995 report on unintended pregnancy concludes, for example, that it is a "health condition of women for which little progress in prevention has been made despite the availability of safe and effective preventive methods."[121] The 2010 Report states that: "there has been no major progress in prevention of unintended pregnancy...."[122]

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[118] IOM Report at 108.

[119] These state laws are discussed in Nat'l Conf. of State Legislatures, *Insurance Coverage for Contraception Laws*, http://www.ncsl.org/issues-re- search/health/insurance-coverage-for-contraception-state-laws.aspx.

[120] Guttmacher Inst., *Facts on Unintended Pregnancy in the United States, supra.*

[121] IOM1995 Report at 104.

[122] Inst. Of Med., *Women's Health Research: Progress, Pitfalls, And Promise* 143 (2010).

HHS' Brief also claims that free contraception and ECs will reduce abortions[123] without offering any sources. Again, this claim seems intuitively true on an individual scale, yet has not succeeded on a national scale. The IOM Report bases its claim upon one Guttmacher study[124] reporting that between 1982 and 2002 there was a 6% rise in the proportion of unmarried women using contraception, and a decline in abortion rates.[125] The study does not address population level effects but only unmarried women, and only for a 20 year period. It variously claims that increased contraceptive usage "accompanied" or "contributed" to diminished abortion rates.[126] It makes no attempt to control for the myriad factors affecting abortion rates at that time such as the economy, mores, the partial-birth abortion debate, and changes in relationship and family structures, to name just a few. This same study admits that early society-wide adoption of contraception often results in "an increase in both contraceptive use and abortion," but claims that over time abortion rates fall.[127] The data does not bear this out. The study only considered data from 1983 to 2002.[128] The chart it references omits the years 1970 to 1982, during which time access to contraception was rising via the federal Title X program, while abortion rates were *climbing* not falling – from 14 per 1,000 women in 1973 to 24 per 1,000 in 1982. It was only after this simultaneous *rise* in rates of contraception usage and abortion rates for about 23

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[123] Brief for Pet. at 47.

[124] Boonstra, *supra*, at 18.

[125] *Id.* at 18.

[126] *Id.*

[127] *Id.* at 19.

[128] *Id.* at 17.

years post-Title X, that abortion rates began to fall, although they remained fairly high, fell slowly, and never fell below their earliest 1970s rates.[129] Also, since their falling began in the early 1990s, they have occasionally ticked up during a few years between 2000 and 2010.[130]

Finally, important material concerning the relationship between contraception and abortion was not mentioned in the Report. First, as described above,[131] some of the drugs and devices covered by the Mandate can destroy human embryos. It is nonsensical to claim that a drug or device that *causes* an early abortion *prevents* abortion. Second, women who use contraception seem more, not less, abortion minded. About 54% of all women seeking abortions were using contraception during the month they became pregnant.[132]

C. Even if free contraception and ECs could lead to fewer unintended pregnancies, HHS has not shown that unintended pregnancy is causally linked with the poor health outcomes for women that HHS claims the Mandate will prevent.

While HHS' Brief does not link unintended pregnancy with negative health outcomes for women,

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[129] Ctrs. for Disease Control, *Abortion Surveillance-U.S. 2000*, 52 Morbidity and Mortality Weekly Rep. No. SS-12, 17 (2003).
[130] Stephanie J. Ventura et al., (CDC), *Estimated Rates of Pregnancy Outcomes for the U.S., 1990-2008*, 9 (June 20, 2012).
[131] *See* Section I., nn 37-39.
[132] Rachel K. Jones et al. (Guttmacher Inst.), *Characteristics Of U.S. Abortion Patients: 2008*, 7-8 (2010), http://www.guttmacher.org/ pubs/US-Abortion-Patients.pdf.

its earlier documents in this litigation assert such a nexus. Neither HHS' arguments, however, nor the IOM Report, demonstrate this nexus. There is further the real scientific possibility, discussed above, that some contraceptives, particularly LARCS, can harm some women, and raise rates of STIs, nonmarital pregnancies and abortion. This raises the question whether the net health effects of the Mandate upon women are positive or negative.

Preliminarily, it should be noted that the IOM's 1995 report on unintended pregnancy acknowledges that "research is limited" on the outcomes from unintended pregnancy, [133] and that extant studies were *not* able to demonstrate "whether the effect is *caused by* or *merely associated with* unwanted pregnancy."[134] Similarly, the leading meta-analysis cited by the IOM Report[135] concluded that "existing evidence on the impact of unintended pregnancy on child and parental health outcomes is mixed and is limited by an insufficient number of studies for some outcomes and by the aforementioned measurement and analytical concerns." [136] On the specific matter of a link between unintended pregnancy and domestic violence or depression, it concluded: "*causality is difficult if not impossible to show.*"[137]

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[133] IOM 1995 Report at 103.

[134] *Id.* at 65. Although the Report insists that it is not important to sort this out, this is both irrational and not the legal standard required in connection with a compelling governmental interest. See Section I.

[135] *See* Jessica D. Gipson et al., *supra.*

[136] *Id.* at 20.

[137] *Id.* (emphasis added).

The lack of causal evidence linking unintended pregnancy with women's smoking and drinking was treated above.[138]

The IOM Report also proposes that domestic violence is a consequence of unintended pregnancy.[139] It cites the IOM's 1995 report for this proposition although that report concluded that relevant studies could *not* establish causation.[140] Furthermore, the 2011 IOM Report failed to divulge studies suggesting *reverse* causation.[141]

HHS does not devote sufficient attention to the possibility that increasing access to contraception might directly harm women's health, though its Brief does acknowledge the serious risks associated with hormonal methods, which constitute a large fraction of FDA-recommended methods.[142] The IOM Report says only that "for women with certain medical conditions or risk factors, some contraceptive methods may be contraindicated,"[143] and that there are "side effects" which are "generally considered minimal."[144] It adds an exception for "oral contraceptive users who smoke."[145] On the matter of women's health, this treatment is insufficient.

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[138] *See supra* nn. 42-44.
[139] IOM Report at 103.
[140] IOM 1995 Report at 65.
[141] Jacquelyn C. Campbell et al., *The Influence of Abuse on Pregnancy Intention*, 5 Women's Health Issues 214 (1995); Patricia M. Dietz et al., *Unintended Pregnancy Among Adult Women Exposed To Abuse Or Household Dysfunction During Their Childhood*, 282 J. Am. Med. Ass'n 1359 (1999).
[142] Brief for Pet. at 48.
[143] IOM Report at 105.
[144] *Id.*
[145] *Id.*

First, increased STI rates have been observed among women given increased pharmacy access to ECs,[146] or LARCs.[147] Second, about 18% of American women smoke.[148] Third, while HHS states that women with particular health difficulties need to avoid pregnancy,[149] it provides no information about their current contraception usage, or how the Mandate might increase it. Also and ironically, HHS fails to note that these *very women* might be at greater risk from more expensive or hormonal contraceptives, given that the medical associations devoted to their conditions recommend avoiding hormonal methods in favor of cheaper barrier or natural methods.[150]

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[146] Christine Piette Durrance, *The Effects of Increased Access to Emergency Contraception on Sexually Transmitted Disease and Abortion Rates*, Economic Inquiry (Dec. 5, 2012), http://onlinelibrary.wiley.com/doi/10.1111/j.1465-7295.2012.00498.x/ abstract.

[147] *See supra*, n. 84.

[148] Am. Lung Ass'n, *Women and Tobacco Use*, http://www.lung.org/stop- smoking/about-smoking/facts-figures/women-and-tobacco-use.html.

[149] Pet. Brief at 47.

[150] *See, e.g., Patient Information: Marfan Syndrome, Heart Disease & Pregnancy*, http://www.heartdiseaseandpregnancy.com/pat_mar_mom.htm; Amer. Congenital Heart Ass'n., *ACHA Q and A: Birth Control for Women with Congenital Heart Disease*, Heart Matters (2008), http://www.achaheart.org/Portals/0/pdf/Library%20Education/ACHA-Q-and-A-Birth-Control-for-Women-with-CHD.pdf (reporting that barrier methods are safe but risks are greater of hormonal methods, especially pills containing estrogen, and certain IUDS); Pulmonary Hypertension Ass'n, *Birth Control And Hormonal Therapy In Pah* (2002), http://www.phassociation.org/document.doc?id=1684 (reporting that barrier methods are "safest" and that "nearly half of ... specialists did not advocate using [pills] for

Fourth, HHS and the IOM Report fail to cite the significant literature about the direct harms caused by some contraceptives. Although modern contraceptive methods are possibly safe in most cases, they injure an unknown number of women every year. While the HHS' Brief concedes serious risks associated with hormonal methods – high blood pressure, heart attacks, blood clots and strokes [151] – it fails to mention that oral contraceptives, IUDs[152] and the Ring[153] have been the subject of myriad class action lawsuits that pharmaceutical corporations have paid hundreds of millions of dollars to settle. It overlooks recent literature showing a 9.5-times greater risk of breast cancer in women using the pill, [154] or indicating that injectable LARCs can double the risk of HIV transmission.[155] It does not

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their patients, and some actively discouraged patients from doing so . . . .").

[151] Brief for Pet. at 48.

[152] *See* Howard Ankin, *Bayer Healthcare Reaches Settlement in Yaz/Yasmin Lawsuits,* Ankin Law Office L.L.C. (May 7, 2012), http://www.ankinlaw.com/blog/bayer- healthcare-reaches-settlement-in-yazyasmin-lawsuits/; *Mirena IUD Lawsuit Update: Mirena IUD Adverse Event Reports to the FDA Exceed 45,000,* SFGATE (Nov. 26, 2012), http://www.sfgate.com/business/prweb/ article/Mirena-IUD-Lawsuit-Update-Mirena-IUD-Adverse-4067514.php#ixzz2GYR9cWxp.

[153] Marie Brenner, *Danger in the Ring*, Vanity Fair (Jan. 2014), http://www.vanityfair.com/politics/2014/01/nuvaring-lethal-contraceptive-trial.

[154] Ajeet Singh Bhadoria, et al., *Reproductive factors and breast cancer: A case-control study in tertiary care hospital of North India*, 50 Ind. J. of Cancer 316 (2013).

[155] Renee Heffron et al., *Use of Hormonal Contraceptives and Risk of HIV-1 Transmission: A Prospective Cohort Study, supra.*

mention that leading cancer associations[156] and the World Health Organization ("WHO") refer to estrogen-progesterone oral contraceptives as "known carcinogens." [157] (The D.C. Court of Appeals considered the WHO finding in rejecting HHS' claim that the Mandate will certainly improve women's health. [158])

In conclusion, HHS has not shown that the Mandate will boost contraceptive usage or that increased usage will reduce rates of unintended pregnancy or abortion. It offers no evidence showing that unintended pregnancy harms women's health in the ways it claims. Even if contraceptives have the indirect beneficial effects HHS identifies, HHS does not indicate the size of these benefits, or whether they outweigh the adverse health outcomes caused by some contraceptives, or the adverse effects of the immiseration of women in a sex and marriage

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[156] Am. Cancer Society, *Known and Probable Human Carcinogens Introduction,* http://www.cancer.org/cancer/cancercauses/othercarcinogens/generalinformationaboutcarcinogens/known-and-probable-human-carcinogens; Int'l Agency for Research on Cancer, *Monographs on the Evaluation of Carcinogenic Risks to Humans,* http://monographs.iarc.fr/ENG/Monographs/vol72/index.php.

[157] World Health Org., *Carcinogenicity of Combined Hormonal Contraceptives and Combined Menopausal Treatment* (2005), http://www.who.int/reproductivehealth/topics/ageing/cocs_hrt_statement.pdf; Steven A. Narod et al., *Oral Contraceptives and the Risk of Breast Cancer in BRCA1 and BRCA2 Mutation Carriers,* 94 J. Nat'l Cancer Inst. 1773 (2002).

[158] *Gilardi v. U.S. Dep't of Health and Hum. Servs.*, No. 13-5069, 26 (D.C. Ct. Apps. Nov. 1, 2013) (referring to the contested evidence about contraceptives' health effects as a "tug-of-war...the government has neither acknowledged nor resolved.").

marketplace shaped by contraception. In other words, the "net" health losses or health benefits of the Mandate are quite uncertain, and HHS has provided no basis for claiming otherwise.

IV. HHS' CLAIMS ABOUT THE MANDATE'S EFFECT ON WOMEN'S EQUAL ACCESS TO HEALTH SERVICES ARE UNPROVEN AND ITS ARGUMENT ABOUT THE MANDATE'S CONTRIBUTION TO WOMEN'S EQUALITY AND SOCIAL INTEGRATION DEMEANS WOMEN.

Citing *Roberts v. United States Jaycees*,[159] HHS argues that "free" contraception and ECs can reduce unequal access between men and women to "recommended health-care services," thereby "removing the barriers to economic advantage and political and social integration" that have "plagued certain disadvantaged groups, including women" and "assur[e] women equal access to ... goods, privileges and advantages."[160] HHS' Memorandum below argued that free contraception and ECs ensure that women are "able to contribute to the same degree as men as healthy and productive members of society."[161] Even assuming that HHS correctly calls contraception a "recommended health-care service," HHS offers no credible scientific sources to support its claim that women have less access to health services due to its costs. Instead HHS cites a U.S. Senator's unsupported statement on women's

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[159] *Roberts v. U.S. Jaycees*, 468 U.S. 609, 626 (1984)).

[160] Brief for Pet. at 49 (citing *Roberts*, *supra*).

[161] Def. Mem. at 25-26.

general health costs,[162] a Medicaid and Medicare Report (which actually attributes the higher health care costs of women of child-bearing years to *maternity care, not contraceptives),* [163] another Senator's unsupported statement about women delaying costly preventive services,[164] and page 19 of the IOM Report which uses sources neither addressing the costs of contraception,[165] nor women's health care costs.[166] In short, HHS provides no evidence whatsoever that the Mandate helps equalize men's and women's health care costs.

Finally, in the name of women's well-being, this Court should refuse to give HHS' second stated interest the status of a "compelling governmental interest." It is demeaning to women to suggest that women's fertility and their bearing and rearing of children, are "barriers" – "plagu[ing]" women's economic, social and political integration, and women's opportunities for "equal access to ... goods, privileges and advantages,"– requiring women's usage of more contraception and ECs. Most women aspire to and do bear and rear children. They build society itself, and need and deserve social support for this important contribution, among others. To agree with HHS that contraception and ECs are indispensable to women's equality, is to deny that society could find another way to assure respect for

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[162] Brief for Pet. at 49-50.

[163] Brief for Pet. at 49. *See* Ctrs. for Medicare & Medicaid Servs., *National Health Care Spending by Gender and Age, 2004 Highlights, supra*, at 1.

[164] Brief for Pet. at 50.

[165] IOM Report at 19.

[166] Henry J. Kaiser Family Found., *Impact of Health Reform on Women's Access to Coverage and Care* (2010), *supra*.

women's innate equality while simultaneously accommodating their aspirations both to be mothers *and* to be economically and politically integrated into society. To affirm HHS' second claimed state interest is also to suggest that the infertile male, or the male without childcare responsibilities, is the norm, and that women attain equality only by conforming to this norm. This Court ought not to breathe life into such a destructive and demeaning notion.

CONCLUSION

For the foregoing reasons, the Court should affirm the judgment of the court of appeals in *Hobby Lobby Stores, Inc.*, and reverse the judgment of the court of appeals in *Conestoga Wood Specialties Corp.*

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Amicus Curiae

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